7.0 510(K) SUMMARY

Submission Date: December 4, 2007

Submitter Information:

Company Name: Or-Nim Medical Ltd.

Company Address: 1 Yodfat Street
Lod, 71291
Israel

Contact Person: Michal Balberg, PhD
Acting Chief Executive Officer and Chief Technical Officer
Or-Nim Medical Ltd.
Tel: +972-8-9282801
Fax: +972-8-9282805
michalb@ornim.com

Device Information:

Trade Name: Pacifica Model 01

Common Name: Oximeter/Cerebral Oximeter/Tissue Oximeter

Classification Name: Oximeter, Tissue Saturation

Device Class: Oximeter, *21 CFR §870.2700*

Predicate Devices: INVOS 5100B (K051274)
Somanetics Corp.
Class II

Adult Cerebral Oximeter Monitor Model 2040 (K051257)
CAS Medical Inc.
Class II

InSpectra StO_2 Tissue Oxygenation Monitor (K061619)
Hutchinson Technology, Inc.
Class II

Device Description: The Pacifica Model 01 uses the well established principles of near infrared spectroscopy (NIRS) to monitor the concentration of oxygenated hemoglobin relative to the total concentration of hemoglobin in the blood. The

Pacifica Model 01 uses three low energy laser light sources for illuminating the tissue at three discrete wavelengths, and measures the optical attenuation of each light wavelength (μ^i, μ^j, μ^k) as a function of depth, in the tissue. From the ratio of differences of the three optical attenuations, the oxygen saturation level is determined.

The Pacifica Model 01 comprises a display and processing unit and a probe that is coupled to the patient using a single use biocompatible adhesive. When the probe is attached to the patient, the system is operated to monitor the tissue blood oxygen saturation level. The probe is connected to the display and processing unit via optical fibers and electronic cables. The display and processing unit includes three separate units (a power unit, a transmitter-receiver unit and a processing unit) and a display.

The Pacifica Model 01 can be operated in two modes: Cerebral mode and Muscle mode. Muscle mode should only be used when the probe is attached to a muscle or soft tissue. Cerebral mode should be used when the probe is applied to the skull

Intended Use:

The Pacifica Model 01 is intended to monitor oxygen saturation of blood in the body.

Indications for Use:

The noninvasive Or-Nim Pacifica Model 01 monitor is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. It is also intended for use as an adjunct monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in adults. The prospective clinical value of data from the Pacifica monitor has not been demonstrated in disease states. The Pacifica monitor should not be used as the sole basis for diagnosis or therapy.

Comparison to Predicate Device:

The Pacifica Model 01 and the cited predicate devices have the same intended use and are used on the same sites of the body. Some technical parameters differ between the Pacifica Model 01 and the predicate devices, but these differences are minor and do not affect safety or effectiveness. Safety and effectiveness evaluations based

on animal and clinical studies indicate the device is substantially equivalent to the predicates cited.

Conclusion: The results of the evaluation of the Pacifica Model 01 support the conclusion that it is as safe and effective as, and is substantially equivalent to, the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Or-Nim Medical, Ltd.
% Becker & Associates Consulting, Inc.
Campbell Hutton
Project Manager
2001 Pennsylvania Avenue, Northwest
Suite 950
Washington, District of Columiba 20006

Re: K073407
Trade/Device Name: Pacifica Model 01
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: MUD
Dated: December 4, 2007
Received: December 4, 2007

Dear Campbell Hutton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6.0 INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K073407

Device Name: Pacifica Model 01

Indications for Use:

The noninvasive Or-Nim Pacifica Model 01 is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain of an adult. It is also intended for use as an adjunct monitor of hemoglobin oxygen saturation of blood in a region of skeletal muscle tissue beneath the sensor in adults. The prospective clinical value of data from the Pacifica monitor has not been demonstrated in disease states. The Pacifica monitor should not be used as the sole basis for diagnosis or therapy.

Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the State in which he / she practices to use or order the use of the device.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073407

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